

Author Index for Volume 21

- Altman, DG, 184S, 488
 Anderson, RT, 171S
 Andriole, GL, 273S
- Babiker, AG, 75
 Bain, RP, 428
 Barrow, S, 356S
 Bautista, OM, 428
 Beck, GJ, 502
 Begg, CB, 241
 Belseck, E, 476
 Bennet, N, 62
 Bhat, N, 349S
 Bjerg, AM, 223
 Bonk, J, 356S
 Borst, C, 595
 Bouchet, C, 30
 Bowen, DJ, 195S, 206S, 226S
 Brandt, CA, 440
 Brawley, LR, 156S, 164S
 Bredée, JJ, 595
 Bresalier, RS, 273S
 Briançon, S, 30
 Broski, KG, 356S
 Browne, JEH, 310S
 Brustia, L, 103
 Bugnard, F, 383
 Buskens, E, 595
 Buys, SS, 273S
 Buyse, M, 415
- Caporaso, N, 349S
 Carroll, RJ, 343
 Caughman, C, 329S
 Chao, D, 212S
 Chappell, R, 138
 Chatellier, G, 383
 Chen, YQ, 369
 Chia, D, 273S
 Childs, J, 356S
 Cohen, S, 171S
 Collins, K, 244
 Colton, T, 415
 Cook, TD, 208
 Crawford, ED, 273S
 Crowley, JJ, 343
 Culos-Reed, SN, 156S, 200S
- Darbyshire, JH, 75
 Dawson, C, 462
 Day, S, 330
 De Amici, D, 103
 de Jaegere, PPT, 595
 de Klerk, E, 540
 de Medina, EOR, 595
 DeMets, DL, 54, 190, 313
 Diephuis, JC, 595
 Dixon, DO, 1
 Dorgan, M, 476
 Dugan, E, 226S
 Dumas, JE, 286
 Dunbar-Jacob, J, 195S
 DYABHYCAR Study group, 383
- Edler, L, 415
 Eefting, FD, 595
 Eknayan, G, 502
 Ellenberg, SS, 498
 Ellis, S, 218S
 Engelhard, D, 356S
 ERA Investigators, 257
 Evans, S, 415
- Fagerstrom, RM, 329S, 390S
 Farmer, D, 212S
 Fazzari, M, 360
 Fijal, BA, 7
 Fink, J, 62
 Fisk, JM, 440
 Flickinger, LM, 329S, 356S
 Fogel, R, 273S
 Ford, ME, 379S
 Fouad, M, 356S, 379S
 Foy, CG, 212S
- Gahagan, B, 356S
 Gamito, E, 356S
 Gassman, JJ, 502
 Geisinger, KR, 257
 Geller, NL, 415
 Gelmann, EP, 273S
 George, SL, 415
 Ghosh, D, 115
 Gilbert, F, 273S
 Gilpin, AK, 462
- Glenny, AM, 488
 Glud, C, 223
 Gohagan, JK, 249S, 251S, 273S, 310S, 349S
 Gong, J, 313
 Gotch, FA, 502
 Gottschau, A, 223
 Greene, T, 502
 Gren, LH, 356S
 Grobbee, DE, 595
 Guillemin, F, 30
- Hall, JM, 7
 Hamilton, G, 62
 Hamilton, SA, 44
 Haralson, JC, 329S
 Harrell, FE Jr, 305
 Hartge, P, 349S
 Hasson, MA, 273S, 329S
 Hayes, RB, 251S, 273S, 349S
 Heller, G, 360
 HEMO Study Group, 502
 Herrington, DM, 257
 Hilke, C, 356S
 Homik, J, 476
 Hoover, RN, 349S
 Hsieh, FY, 552
 Hutton, JL, 415
- Ibrahim, JG, 574
 Iglewicz, B, 127
 INFO Trial Group, The, 223
 ISCB Subcommittee on Fraud, 415
- Jamrozik, K, 244
 Jansen, EWL, 595
 Jernigan, JC, 379S
 Johnson, BF, 62
 Johnson, CC, 273S, 349S, 356S
- Kahane, DC, 329S
 Kaplan, RM, 233S
 Karras, BT, 440
 Kealey, KA, 144
 Kidd, KE, 184S

Author Index for Volume 21

- Altman, DG, 184S, 488
 Anderson, RT, 171S
 Andriole, GL, 273S
- Babiker, AG, 75
 Bain, RP, 428
 Barrow, S, 356S
 Bautista, OM, 428
 Beck, GJ, 502
 Begg, CB, 241
 Belseck, E, 476
 Bennet, N, 62
 Bhat, N, 349S
 Bjerg, AM, 223
 Bonk, J, 356S
 Borst, C, 595
 Bouchet, C, 30
 Bowen, DJ, 195S, 206S, 226S
 Brandt, CA, 440
 Brawley, LR, 156S, 164S
 Bredée, JJ, 595
 Bresalier, RS, 273S
 Briançon, S, 30
 Broski, KG, 356S
 Browne, JEH, 310S
 Brustia, L, 103
 Bugnard, F, 383
 Buskens, E, 595
 Buys, SS, 273S
 Buyse, M, 415
- Caporaso, N, 349S
 Carroll, RJ, 343
 Caughman, C, 329S
 Chao, D, 212S
 Chappell, R, 138
 Chatellier, G, 383
 Chen, YQ, 369
 Chia, D, 273S
 Childs, J, 356S
 Cohen, S, 171S
 Collins, K, 244
 Colton, T, 415
 Cook, TD, 208
 Crawford, ED, 273S
 Crowley, JJ, 343
 Culos-Reed, SN, 156S, 200S
- Darbyshire, JH, 75
 Dawson, C, 462
 Day, S, 330
 De Amici, D, 103
 de Jaegere, PPT, 595
 de Klerk, E, 540
 de Medina, EOR, 595
 DeMets, DL, 54, 190, 313
 Diephuis, JC, 595
 Dixon, DO, 1
 Dorgan, M, 476
 Dugan, E, 226S
 Dumas, JE, 286
 Dunbar-Jacob, J, 195S
 DYABHYCAR Study group, 383
- Edler, L, 415
 Eefting, FD, 595
 Eknayan, G, 502
 Ellenberg, SS, 498
 Ellis, S, 218S
 Engelhard, D, 356S
 ERA Investigators, 257
 Evans, S, 415
- Fagerstrom, RM, 329S, 390S
 Farmer, D, 212S
 Fazzari, M, 360
 Fijal, BA, 7
 Fink, J, 62
 Fisk, JM, 440
 Flickinger, LM, 329S, 356S
 Fogel, R, 273S
 Ford, ME, 379S
 Fouad, M, 356S, 379S
 Foy, CG, 212S
- Gahagan, B, 356S
 Gamito, E, 356S
 Gassman, JJ, 502
 Geisinger, KR, 257
 Geller, NL, 415
 Gelmann, EP, 273S
 George, SL, 415
 Ghosh, D, 115
 Gilbert, F, 273S
 Gilpin, AK, 462
- Glenny, AM, 488
 Glud, C, 223
 Gohagan, JK, 249S, 251S, 273S, 310S, 349S
 Gong, J, 313
 Gotch, FA, 502
 Gottschau, A, 223
 Greene, T, 502
 Gren, LH, 356S
 Grobbee, DE, 595
 Guillemin, F, 30
- Hall, JM, 7
 Hamilton, G, 62
 Hamilton, SA, 44
 Haralson, JC, 329S
 Harrell, FE Jr, 305
 Hartge, P, 349S
 Hasson, MA, 273S, 329S
 Hayes, RB, 251S, 273S, 349S
 Heller, G, 360
 HEMO Study Group, 502
 Herrington, DM, 257
 Hilke, C, 356S
 Homik, J, 476
 Hoover, RN, 349S
 Hsieh, FY, 552
 Hutton, JL, 415
- Ibrahim, JG, 574
 Iglewicz, B, 127
 INFO Trial Group, The, 223
 ISCB Subcommittee on Fraud, 415
- Jamrozik, K, 244
 Jansen, EWL, 595
 Jernigan, JC, 379S
 Johnson, BF, 62
 Johnson, CC, 273S, 349S, 356S
- Kahane, DC, 329S
 Kaplan, RM, 233S
 Karras, BT, 440
 Kealey, KA, 144
 Kidd, KE, 184S

- King, DW, 94
 Kjaergard, LL, 223
 Klein, KP, 257
 Klersy, C, 103
 Knape, JTA, 595
 Kopp, W, 349S
 Kramer, BS, 251S
 Krogsgaard, K, 223
 Kruse, AY, 223
 Kusek, JW, 502
 KyungMann, K, 190
- Lachenbruch, P, 415
 Lachin, JM, 167, 428
 Lagakos, SW, 1
 Lamerato, L, 356S
 Lan, KKG, 190
 Lappe, K, 356S
 Lashley, R, 94
 Laughlin, JE, 286
 Lavori, PW, 552
 Legedza, ATR, 574
 Lesaffre, E, 415, 540
 Levey, AS, 502
 Levin, DL, 310S
 Levin, NW, 502
 Lew, R, 62
 Lièvre, M, 383
 Lu, C, 440
 Lu, J, 561
 Lucey, G, 62
- Mandel, JS, 273S
 Mann, SL, 144
 Marek, PM, 144
 Marengo, L, 440
 Marre, M, 383
 Martin, J, 356S
 Martin, KA, 195S
 MASTER Trial Study Group, 244
 McAuley, E, 164S, 200S
 McBride, JS, 171S
 McGuire, C, 356S
 McMahon, RP, 305
 Meinert, CL, 462
 Mick, R, 343
 Miller, AB, 400S
 Miller, DS, 379S
 Miller, PL, 440
 Mortensen, EL, 223
 Murray, G, 415
- Myers, MH, 329S
 Myles, PS, 244
- Nadkarni, P, 440
 Nathoe, HM, 595
 Nichaman, L, 310S
 Nierich, AP, 595
- O'Brien, B, 273S, 310S, 390S
 Oberman, A, 273S
 Ockene, JK, 200S, 206S
 Ogden, SL, 356S
 Oken, MM, 273S
 Ory, M, 171S
- Pajak, TF, 561
 Palace, C, 349S
 Parsons, RW, 244
 Paul-Dauphin, A, 30
 Perri, MG, 195S, 206S
 Peterson, AV Jr, 144
 Peyton, P, 244
 Pharmacological Intervention Working Group, 218S
 Pinheiro, JC, 313
 Plouin, PF, 383
 Politi, P, 103
 Prinz, RJ, 286
 Prorok, PC, 251S, 273S, 310S
 Proschan, MA, 527
- Raab, GM, 330
 Radial Artery Patency Study Investigators, 397
 Rafla, S, 273S
 Ramajoli, F, 103
 Ramos-Remus, C, 476
 Rand, CS, 188S, 218S, 241
 Ranstam, J, 415
 Rapp, SR, 164S, 188S
 Reboussin, DM, 190, 257
 Reding, D, 273S, 349S
 Réglier, JC, 383
 Rejeski, WJ, 155S, 164S, 200S
 Ribisl, PM, 188S
 Richardson, L, 383
 Rigg, JRA, 244
 Rosal, MC, 206S
 Roter, DL, 200S
- Rothman, N, 349S
 Rutt, W, 273S
- Sales, J, 330
 Schacter, L, 440
 Scher, HI, 360
 Scherrer, B, 415
 Schulman, G, 502
 Schwemer, G, 21
 Sevick, MA, 188S, 206S, 241S
 Sharp, PC, 257
 Sherman, AM, 206S
 Shumaker, SA, 155S, 218S, 226S, 257
 Sieber, WJ, 218S, 233S
 Silbert, B, 244
 Simpson, NK, 356S, 379S
 Smith, EP, 286
 Snyder, TE, 257
 Song, F, 488
 Stallings, FL, 379S
 Suarez-Almazor, ME, 476
 Subar, AF, 349S
 Sullivan, D, 356S
- Thompson, J, 356S
 Trauth, JM, 379S
 Trocky, N, 356S
 Turner, LM, 329S
- Ünalp, A, 462
- van Dijk, D, 595
 Vasmant, D, 383
 Vitolins, MZ, 188S, 206S
- Waclawiw, MA, 527
 Walker, AS, 75
 Walsh, JH, 329S
 Wang, MC, 369
 Weissfeld, JL, 273S, 349S, 390S, 400S
 Wenzel, B, 329S
 Wiens, BL, 127
 Witte, JS, 7
- Yokochi, L, 273S
 Yurgalevitch, S, 400S
- Ziegler, RG, 349S

Subject Index for Volume 21

ACCELERATED HAZARDS MODELS

Estimating the Treatment Effect with the Accelerated Hazards Models, 369

ADHERENCE

- A Design for Testing Interventions to Improve Adherence Within a Hypertension Clinical Trial, 62
- Adherence in Social Context, 184S
- Adherence to Pharmacological Interventions: Current Trends and Future Directions, 218S
- Dietary Adherence: Characteristics and Interventions, 206S
- Enhancing Adherence in Randomized Controlled Clinical Trials, 226S
- Estimating the Power of Compliance—Improving Methods, 540
- Ethics in Adherence Promotion and Monitoring, 241S
- Exercise Adherence among Older Adults: Challenges and Strategies, 212S
- Informed Adherence: The Need for Shared Medical Decision Making, 233S
- Issues of Aging and Adherence to Health Interventions, 171S
- Measuring Adherence to Behavioral and Medical Interventions, 188S
- Predictors of Adherence to Behavioral Change Interventions in the Elderly, 200S
- Studying Adherence to Therapeutic Regimens: Overview, Theories, Recommendations, 156S
- Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

AGING. *See also* ELDERLY

Issues of Aging and Adherence to Health Interventions, 171S

AIDS

Analysis of Multivariate Failure-time-Data from HIV Clinical Trials, 75

Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7

ANESTHESIA

- Design of the Multicenter Australian Study of Epidural Anesthesia and Analgesia in Major Surgery: The MASTER Trial, 244
- Impact of the Hawthorne Effect in a Longitudinal Clinical Study: The Case of Anesthesia, 103

ATHEROSCLEROSIS

- Multicenter Radial Artery Patency Study (RAPS): Study design, 397
- The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

AZT TREATMENT

Analysis of Multivariate Failure-time Data from HIV Clinical Trials, 75

BEHAVIOR CHANGE INTERVENTION

- Adherence to Pharmacological Interventions: Current Trends and Future Directions, 218S
- An Examination of Theory and Behavior Change in Randomized Clinical Trials, 164S
- Dietary Adherence: Characteristics and Interventions, 206S
- Exercise Adherence among Older Adults: Challenges and Strategies, 212S
- Measuring Adherence to Behavioral and Medical Interventions, 188S
- Predictors of Adherence to Behavioral Change Interventions in the Elderly, 200S
- Studying Adherence to Therapeutic Regimens: Overview, Theories, Recommendations, 156S

Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

BETA DISTRIBUTION

Estimating the Power of Compliance—Improving Methods, 540

BIAS. See GENDER BIAS

BIOSTATISTICS

Fraud in Medical Research: An International Survey of Biostatisticians, 415

BONFERRONI METHOD

Estimating Significance Level and Power Comparisons for Testing Multiple Endpoints in Clinical Trials, 313

Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527

BOOK REVIEWS

Applied Survival Analysis, 56

Basic Statistics and Pharmaceutical Statistical Applications, 593

Cardiovascular Drug Development: Protocol Design and Methodology, 140

CANCER SCREENING

Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S

Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S

Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S

Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S

Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S

Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S

Informed Adherence: The Need for Shared Medical Decision Making, 233S

Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S

Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S

The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S

The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

CANCER TREATMENTS

Phase II Clinical Trial Design for Noncytotoxic Anticancer Agents for Which Time to Disease Progression is the Primary Endpoint, 343

The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360

CARDIOVASCULAR DISEASE

Adjusting Survival Analysis for the Presence of Unadjudicated Study Events, 208

Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527

The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

The Non-Insulin-Dependent Diabetes, Hypertension, Microalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383

The Octopus Study: Rationale and Design of Two Randomized Trials on Medical Effectiveness, Safety, and Cost Effectiveness of Bypass Surgery on the Beating Heart, 595

CHILDHOOD CONDUCT DISORDERS

The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct

Problems, Substance Abuse, and
School Failure in Childhood, 286

COLORECTAL CANCER

Black Participation in the Prostate, Lung,
Colorectal and Ovarian (PLCO)
Cancer Screening Trial, 379S

Coordination and Management of a
Large Multicenter Screening
Trial: The PLCO Cancer Screening
Trial, 310S

Death Review Process in the Prostate,
Lung, Colorectal and Ovarian
(PLCO) Cancer Screening Trial,
400S

Design and Evolution of the Data
Management Systems in the
PLCO Cancer Screening Trial,
329S

Design of the Prostate, Lung, Colorectal
and Ovarian (PLCO) Cancer
Screening Trial, 273S

Etiologic and Early Marker Studies in the
Prostate, Lung, Colorectal and
Ovarian (PLCO) Cancer Screening
Trial, 349S

Identifying Clinical Trials in the Medical
Literature with Electronic
Databases: MEDLINE Alone is
Not Enough, 476

Indirect Comparison in Evaluating
Relative Efficacy Illustrated by
Antimicrobial Prophylaxis in
Colorectal Surgery, 488

Quality Control of Cancer Screening
Examination Procedures in the
PLCO Cancer Screening Trial,
390S

Recruitment Strategies in the Prostate,
Lung, Colorectal and Ovarian
(PLCO) Cancer Screening Trial:
The First 6 Years, 356S

Reengineering a Database for Clinical
Trials Management: Lessons for
System Architects, 440

The PLCO Cancer Screening Trial of the
National Cancer Institute:
History, Organization, and
Status, 251S

The Prostate, Lung, Colorectal and
Ovarian (PLCO) Cancer
Screening Trial, 249S

COMPLIANCE. *See* ADHERENCE

CONDITIONAL POWER

A Flexible Stochastic Curtailing
Procedure for the Log-Rank
Test, 428

CONTINUAL REASSESSMENT METHOD

Longitudinal Design for Phase I Clinical
Trials Using the Continual
Reassessment Method, 574

CONTINUOUS SAMPLING PLANS

A Quantifiable Alternative to Double
Data Entry, 94

CORONARY BYPASS SURGERY

Multicenter Radial Artery Patency Study
(RAPs): Study design, 397

The Octopus Study: Rationale and Design
of Two Randomized trials on
Medical Effectiveness, Safety, and
Cost Effectiveness of Bypass
Surgery on the Beating Heart, 595

CORONARY HEART DISEASE. *See* CARDIOVASCULAR DISEASE

COVARIANCE ANALYSIS

How to Select Covariates to Include in
the Analysis of a Clinical Trial,
330

COX REGRESSION MODELS

Design and Statistical Issues of the
Hemodialysis (HEMO) Study,
502

CUMULATIVE INCIDENCE

Methods for Analysis of Multiple Events
in the Presence of Death, 115

CYTOSTATIC AGENTS

Phase II Clinical Trial Design for
Noncytotoxic Anticancer Agents
for Which Time to Disease
Progression is the Primary
Endpoint, 343

DATA MANAGEMENT

Coordination and Management of a
Large Multicenter Screening
Trial: The PLCO Cancer Screening
Trial, 310S

Design and Evolution of the Data
Management Systems in the
PLCO Cancer Screening Trial,
329S

DEATH

Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S

Methods for Analysis of Multiple Events in the Presence of Death, 115

DESIGN PAPERS

A Design for Testing Interventions to Improve Adherence Within a Hypertension Clinical Trial, 62

Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502

Design of the Multicenter Australian Study of Epidural Anesthesia and Analgesia in Major Surgery: The MASTER Trial, 244

Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S

Experimental Design and Methods for School-Based Randomized Trials: Experience from the Hutchinson Smoking Prevention Project (HSPP), 144

Multicenter Radial Artery Patency Study (RAPS): Study design, 397

The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct Problems, Substance Abuse, and School Failure in Childhood, 286

The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

The Non-Insulin-Dependent Diabetes, Hypertension, Microalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383

The Octopus Study: Rationale and Design of Two Randomized trials on Medical Effectiveness, Safety, and Cost Effectiveness of Bypass Surgery on the Beating Heart, 595

DIABETES

The Non-Insulin-Dependent Diabetes, Hypertension, Microalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study:

Design, Organization, and Patient Recruitment, 383

DIALYSIS

Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502

DIET

Dietary Adherence: Characteristics and Interventions, 206S

Measuring Adherence to Behavioral and Medical Interventions, 188S

Predictors of Adherence to Behavioral Change Interventions in the Elderly, 200S

Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

DISEASE SUSCEPTIBILITY

Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7

DOUBLE DATA ENTRY

A Quantifiable Alternative to Double Data Entry, 94

DYNAMIC RANDOMIZATION

Dynamically Allocating Treatment When the Cost of Goods Is High and Drug Supply Is Limited, 44

EFFICACY ANALYSIS

Commentary: Ruminations on the Intent-to-Treat Principle, 241

Indirect Comparison in Evaluating Relative Efficacy Illustrated by Antimicrobial Prophylaxis in Colorectal Surgery, 488

Statistical Considerations in the Intent-to-Treat Principle, 167

ELDERLY

Adherence in Social Context, 184S

Adherence to Pharmacological Interventions: Current Trends and Future Directions, 218S

Exercise Adherence among Older Adults: Challenges and Strategies, 212S

Issues of Aging and Adherence to Health Interventions, 171S

Predictors of Adherence to Behavioral Change Interventions in the Elderly, 200S

Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

ELECTRONIC DATABASES

Gender Representation in Trials, 462
Identifying Clinical Trials in the Medical Literature with Electronic Databases: MEDLINE Alone is Not Enough, 476

EPIDURAL ANALGESIA

Design of the Multicenter Australian Study of Epidural Anesthesia and Analgesia in Major Surgery: The MASTER Trial, 244

EQUIVALENCE OF TREATMENTS

Design and Analysis of Three Treatment Equivalence Trials, 127

ESTROGEN REPLACEMENT THERAPY

The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

ETHICS

Ethics in Adherence Promotion and Monitoring, 241S

ETIOLOGY

Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S

EVENT CLASSIFICATION

Adjusting Survival Analysis for the Presence of Unadjudicated Study Events, 208

EXERCISE. See PHYSICAL ACTIVITY

FAILURE TIMES

Phase II Clinical Trial Design for Noncytotoxic Anticancer Agents for Which Time to Disease Progression is the Primary Endpoint, 343

FAMILYWISE ERROR RATE

Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527

FRAUD. See SCIENTIFIC FRAUD

GENDER BIAS

Gender Representation in Trials, 462

GENERALIZABILITY

General Linear Models for Multicenter Clinical Trials, 21
Indirect Comparison in Evaluating Relative Efficacy Illustrated by Antimicrobial Prophylaxis in Colorectal Surgery, 488

GENETIC SCREENING

Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S

GLOBAL TEST

Estimating Significance Level and Power Comparisons for Testing Multiple Endpoints in Clinical Trials, 313

GROUP SEQUENTIAL ANALYSIS

Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561

HAWTHORNE EFFECT

Impact of the Hawthorne Effect in a Longitudinal Clinical Study: The Case of Anesthesia, 103

HEALTH INTERVENTION

Adherence in Social Context, 184S
Issues of Aging and Adherence to Health Interventions, 171S
Measuring Adherence to Behavioral and Medical Interventions, 188S
Selection of Quality-of-Life Measures for a Prevention Trial: A Psychometric Analysis, 30

HIV INFECTION

- Analysis of Multivariate Failure-time Data from HIV Clinical Trials, 75
- Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7

HYPERTENSION

- A Design for Testing Interventions to Improve Adherence Within a Hypertension Clinical Trial, 62

INDIRECT COMPARISONS

- Indirect Comparison in Evaluating Relative Efficacy Illustrated by Antimicrobial Prophylaxis in Colorectal Surgery, 488

INFORMATION SHARING

- Commentary: Relationships Between Data Monitoring Committees, 54

INFORMED CONSENT

- Ethics in Adherence Promotion and Monitoring, 241S
- Impact of the Hawthorne Effect in a Longitudinal Clinical Study: The Case of Anesthesia, 103

INTENT TO TREAT

- Commentary: Ruminations on the Intent-to-Treat Principle, 241
- Statistical Considerations in the Intent-to-Treat Principle, 167

INTERACTION

- General Linear Models for Multicenter Clinical Trials, 21

INTERIM ANALYSIS

- Adjusting Survival Analysis for the Presence of Unadjudicated Study Events, 208
- Should Data and Safety Monitoring Boards Share Confidential Interim Data?, 1

INTERNET

- Reengineering a Database for Clinical Trials Management: Lessons for System Architects, 440

INTERVENTION. See SCHOOL-BASED INTERVENTION**LOG-RANK TEST**

- A Flexible Stochastic Curtailing Procedure for the Log-Rank Test, 428
- Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561

LONGITUDINAL DESIGN

- Longitudinal Design for Phase I Clinical Trials Using the Continual Reassessment Method, 574

LUNG CANCER

- Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
- Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
- Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
- Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S
- Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
- Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
- Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S
- Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
- The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S
- The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

MALIGNANT GLIOMAS

- Estimating the Treatment Effect with the Accelerated Hazards Models, 369

MARGINAL MODELS

Analysis of Multivariate Failure-time
Data from HIV Clinical Trials, 75

MEDLINE

Gender Representation in Trials, 462
Identifying Clinical Trials in the Medical
Literature with Electronic
Databases: MEDLINE Alone is
Not Enough, 476

MINORITY GROUPS

Black Participation in the Prostate, Lung,
Colorectal and Ovarian (PLCO)
Cancer Screening Trial, 379S

MISSING DATA

Power Calculation for Clinical Trials
When the Outcome Is a
Composite Ranking of Survival
and a Nonfatal Outcome, 305
The Estrogen Replacement and
Atherosclerosis (ERA) Study: Study
Design and Baseline
Characteristics of the Cohort, 257

MIXTURE MODEL

Estimating the Power of
Compliance—Improving
Methods, 540

MONITORING

A Quantifiable Alternative to Double
Data Entry, 94
Commentary: Relationships between
Data Monitoring Committees, 54
Should Data and Safety Monitoring
Boards Share Confidential
Interim Data?, 1

MULTICENTER TRIALS

Coordination and Management of a
Large Multicenter Screening
Trial: The PLCO Cancer Screening
Trial, 310S
Gender Representation in Trials, 462
General Linear Models for Multicenter
Clinical Trials, 21

MULTIPLE COMPARISONS

Design and Analysis of Three Treatment
Equivalence Trials, 127
Practical Guidelines for Multiplicity
Adjustment in Clinical Trials, 527

MULTIPLE EVENTS

Methods for Analysis of Multiple Events
in the Presence of Death, 115

MULTIPLE OUTCOMES

Estimating Significance Level and Power
Comparisons for Testing
Multiple Endpoints in Clinical
Trials, 313
Power Calculation for Clinical Trials
When the Outcome Is a
Composite Ranking of Survival
and a Nonfatal Outcome, 305

**MULTIVARIATE FAILURE-TIME
DATA**

Analysis of Multivariate Failure-time
Data from HIV Clinical Trials, 75

NEUROPSYCHOLOGICAL TESTS

The Octopus Study: Rationale and Design
of Two Randomized trials on
Medical Effectiveness, Safety, and
Cost Effectiveness of Bypass
Surgery on the Beating Heart, 595

NONBINARY COVARIATES

Sample-Size Calculations for the Cox
Proportional Hazards
Regression Model with Nonbinary
Covariates, 552

NUTRITION. See DIET**OLDER ADULTS. See ELDERLY****ORAL POTASSIUM**

A Design for Testing Interventions to
Improve Adherence Within a
Hypertension Clinical Trial, 62

OUTCOMES MODEL

Informed Adherence: The Need for
Shared Medical Decision
Making, 233S

OVARIAN CANCER

Black Participation in the Prostate, Lung,
Colorectal and Ovarian (PLCO)
Cancer Screening Trial, 379S
Coordination and Management of a
Large Multicenter Screening
Trial: The PLCO Cancer Screening
Trial, 310S

- Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
- Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329
- Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
- Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
- Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S
- Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
- The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S
- The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

PATIENT INFORMATION

- A Randomized Trial Assessing the Impact of Written Information on Outpatients' Knowledge About and Attitude Toward Randomized Clinical Trials, 223

PATIENT RECORD SYSTEMS

- Reengineering a Database for Clinical Trials Management: Lessons for System Architects, 440

PATIENT RECRUITMENT AND SELECTION

- Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
- Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
- The Non-Insulin-Dependent Diabetes, Hypertension, Microalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383

PHARMACOLOGY

- Adherence to Pharmacological Interventions: Current Trends and Future Directions, 218S
- Measuring Adherence to Behavioral and Medical Interventions, 188S
- Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

PHASE I TRIALS

- Longitudinal Design for Phase I Clinical Trials Using the Continual Reassessment Method, 574

PHASE II TRIALS

- Phase II Clinical Trial Design for Noncytotoxic Anticancer Agents for Which Time to Disease Progression is the Primary Endpoint, 343
- The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360

PHYSICAL ACTIVITY

- Exercise Adherence among Older Adults: Challenges and Strategies, 212S
- Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

POOLING

- General Linear Models for Multicenter Clinical Trials, 21

PREVENTION TRIALS

- Enhancing Adherence in Randomized Controlled Clinical Trials, 226S
- Experimental Design and Methods for School-Based Randomized Trials: Experience from the Hutchinson Smoking Prevention project (HSPP), 144
- The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct Problems, Substance Abuse, and School Failure in Childhood, 286

PROPORTIONAL HAZARDS REGRESSION

- Sample-Size Calculations for the Cox Proportional Hazards Regression Model with Nonbinary Covariates, 552

PROSTATE CANCER

- Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
- Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
- Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
- Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S
- Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
- Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
- Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S
- Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
- Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561
- The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360
- The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S
- The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

PROTECTIVE GENES

- Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7

PSORIASIS

- How to Select Covariates to Include in the Analysis of a Clinical Trial, 330

PSYCHOMETRIC PROPERTIES

- Selection of Quality-of-Life Measures for a Prevention Trial: A Psychometric Analysis, 30

QUALITY ASSURANCE

- A Quantifiable Alternative to Double Data Entry, 94
- Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
- Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S

QUALITY OF LIFE

- Selection of Quality-of-Life Measures for a Prevention Trial: A Psychometric Analysis, 30

QUESTIONNAIRES

- A Randomized Trial Assessing the Impact of Written Information on Outpatients' Knowledge About and Attitude Toward Randomized Clinical Trials, 223
- Commentary: Fraud Is Bad, Studying Fraud Is Hard, 498
- Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
- Fraud in Medical Research: An International Survey of Biostatisticians, 415

RADIAL ARTERY

- Multicenter Radial Artery Patency Study (RAPS): Study Design, 397

RAMIPRIL

- The Non-Insulin-Dependent Diabetes, Hypertension, Microalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383

RECURRENT EVENTS

- Methods for Analysis of Multiple Events in the Presence of Death, 115

RENAL DISEASE

- Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502
- Issues of Aging and Adherence to Health Interventions, 171S

REPEATED MEASURES

Computations for Group Sequential
Boundaries Using the Lan-
DeMets Spending Function
Method, 190

RETENTION

Enhancing Adherence in Randomized
Controlled Clinical Trials, 226S

RHEUMATIC DISEASES

Gender Representation in Trials, 476

SAMPLE SIZE

Clinical Trials in the Genomic Era: Effects
of Protective Genotypes on
Sample Size and Duration of
Trial, 7

Sample-Size Calculations for the Cox
Proportional Hazards
Regression Model with Nonbinary
Covariates, 552

The Phase II/III Transition: Toward the
Proof of Efficacy in Cancer
Clinical Trials, 360

SCHOLARSHIPS

Commentary: Student Scholarship
Competition Manuscripts:
Relevance, Rigor, and Promise,
138

SCHOOL-BASED INTERVENTION

Experimental Design and Methods for
School-Based Randomized
Trials: Experience from the
Hutchinson Smoking Prevention
project (HSPP), 144

The EARLY ALLIANCE Prevention
Trial: A Dual Design to Test
Reduction of Risk for Conduct
Problems, Substance Abuse, and
School Failure in Childhood, 286

SCIENTIFIC FRAUD

Commentary: Fraud Is Bad, Studying
Fraud Is Hard, 498
Fraud in Medical Research: An
International Survey of
Biostatisticians, 415

SELECTION BIAS

Statistical Considerations in the Intent-to-
Treat Principle, 167

SELF-EFFICACY THEORY

Studying Adherence to Therapeutic
Regimens: Overview, Theories,
Recommendations, 156S

SENSITIVITY ANALYSIS

Statistical Considerations in the Intent-to-
Treat Principle, 167

SMOKING PREVENTION

Experimental Design and Methods for
School-Based Randomized
Trials: Experience from the
Hutchinson Smoking Prevention
project (HSPP), 144

SOCIAL-COGNITIVE THEORY

Studying Adherence to Therapeutic
Regimens: Overview, Theories,
Recommendations, 156S

SOFTWARE DESIGN

Design and Evolution of the Data
Management Systems in the
PLCO Cancer Screening Trial,
329S

SPENDING FUNCTION

Computations for Group Sequential
Boundaries Using the Lan-
DeMets Spending Function
Method, 190

STATISTICAL POWER

Computations for Group Sequential
Boundaries Using the Lan-
DeMets Spending Function
Method, 190

Statistical Power for a Long-Term
Survival Trial with a Time-
Dependent Treatment Effect, 561

STENT IMPLANTATION

The Octopus Study: Rationale and Design
of Two Randomized trials on
Medical Effectiveness, Safety, and
Cost Effectiveness of Bypass
Surgery on the Beating Heart, 595

STOCHASTIC CURTAILING

A Flexible Stochastic Curtailing
Procedure for the Log-Rank
Test, 428

STUDY DESIGN

Reengineering a Database for Clinical Trials Management: Lessons for System Architects, 440

SUBSTANCE ABUSE

The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct Problems, Substance Abuse, and School Failure in Childhood, 286

SURROGATE ENDPOINTS

The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360

SURVIVAL ANALYSIS

A Flexible Stochastic Curtailing Procedure for the Log-Rank Test, 428

Adjusting Survival Analysis for the Presence of Unadjudicated Study Events, 208

Computations for Group Sequential Boundaries Using the Lan-DeMets Spending Function Method, 190

TERMINAL EVENT. *See* DEATH

THEORY DEVELOPMENT

An Examination of Theory and Behavior Change in Randomized Clinical Trials, 164S

Studying Adherence to Therapeutic Regimens: Overview, Theories, Recommendations, 156S

TIME-DEPENDENT TREATMENT EFFECT

Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561

TOXICITY

Longitudinal Design for Phase I Clinical Trials Using the Continual Reassessment Method, 574

TREATMENT

Design and Analysis of Three Treatment Equivalence Trials, 127

Dynamically Allocating Treatment When the Cost of Goods Is High and Drug Supply Is Limited, 44

TYPE I ERROR

Computations for Group Sequential Boundaries Using the Lan-DeMets Spending Function Method, 190

Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527

Statistical Considerations in the Intent-to-Treat Principle, 167

UREA KINETIC MODELING

Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502

VARIABLE SELECTION

How to Select Covariates to Include in the Analysis of a Clinical Trial, 330

VARIANCE INFLATION FACTOR

Sample-Size Calculations for the Cox Proportional Hazards Regression Model with Nonbinary Covariates, 552

VISUAL RECORD VERIFICATION

A Quantifiable Alternative to Double Data Entry, 94

WOMEN'S HEALTH

Gender Representation in Trials, 462

The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

WORST-RANK TEST

Power Calculation for Clinical Trials When the Outcome Is a Composite Ranking of Survival and a Nonfatal Outcome, 305

